STILLMEADOW
INCORPORATED

VOLUME __ OF __ OF SUBMISSION

Niccanon ZP700

FINAL REPORT

ACUTE EYE IRRITATION STUDY IN RABBITS

OCSPP NO. 870.2400 and OECD 405

AUTHOR:

Janice O. Kuhn, PhD, DABT

STUDY INITIATION DATE: 10 January 2012
STUDY COMPLETION DATE: 30 April 2012

CONDUCTED BY:
STILLMEADOW, Inc.
12852 Park One Drive
Sugar Land, TX 77478

LABORATORY STUDY NUMBER:

15888-11

VOLUME 1 OF 1 OF STUDY

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SPONSOR:
Nicca USA, Inc.
c/o Arch Chemicals
501 Merritt 7
Norwalk, CT 06856

STATEMENT OF NO DATA CONFIDENTIALITY CLAIM

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10 (d) (1) (A), (B) or (C).

Company: Nicca USA, Inc.

Company Agent: _____ Date: _____

_____

Title Signature

These data are the property of Nicca USA, Inc., and as such, are considered to be confidential for all purposes other than compliance with FIFRA § 10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality that may exist under any other statute or in any other country.

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study was designed and performed at STILLMEADOW, Inc. and was conducted in compliance with United States Environmental Protection Agency FIFRA 40 CFR 160 with exception of:
Section 160.31 (d) and 160.105 (a) The provided Certificate of Analysis was not accompanied by a GLP compliance statement.
Section 160.31 (d) and 160.105 (b)(e) Stability information was not provided to the testing facility.

This study was designed and performed at STILLMEADOW, Inc. and was conducted in compliance with United States Environmental Protection Agency TSCA 40 CFR 792 with exception of:
Section 792.31 (d) and 792.105 (a) The provided Certificate of Analysis was not accompanied by a GLP compliance statement.
Section 792.31 (d) and 792.105 (b)(e) Stability information was not provided to the testing facility.

This study was designed and performed at STILLMEADOW, Inc. and was conducted in compliance with Organization for Economic Cooperation & Development Principles of GLP, Annex 2, C(98)17 with exception of:
Section II, 1.1 (2)(p), 6.1 (1) and 6.2 (2) The provided Certificate of Analysis was not accompanied by a GLP compliance statement.
Section II, 6.2 (4) Stability information was not provided to the testing facility.

Janice O. Kuhn

Janice O. Kuhn, PhD, DABT
Study Director, STILLMEADOW, Inc.

30 Apr 12
Date

Nicholas R. Skoulis

Signature of Agent of Sponsor

15 May 12
Date

Nicholas P. Skoulis

Agent Name
Sponsor: Nicca USA, Inc.

Signature of Agent of Submitter

Date

Agent Name
Submitter: Arch Chemicals

QUALITY ASSURANCE STATEMENT

Test Substance: Niccanon ZP700
Study Title: Acute Eye Irritation Study in Rabbits

The study report and data have been audited in accordance with Good Laboratory Practice Standards and STILLMEADOW, Inc. Standard Operating Procedures (SOPs). The final report accurately reflects the study data. The Quality Assurance Unit has not been involved in the actual conduct of this study.

The Quality Assurance Unit performed a recent facility inspection on 23 Jan 12. All findings were reported to Management, and the report and responses are kept in the Quality Assurance files.

The findings from any study inspections and audits were reported to the Study Director and Management as follows:

Critical Phase Inspected	Date Inspected	Reported to Study Director	Reported to Management
Protocol Review	20 Dec 11	20 Dec 11	20 Dec 11
Dosing	20 Feb 12	20 Feb 12	20 Feb 12
Report/Data Audit	23 Mar 12	23 Mar 12	23 Mar 12

Kristina Rodrigue

Kristina Rodrigue, RQAP-GLP
Quality Assurance, STILLMEADOW, Inc.

30 Apr 12

Date

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SUMMARY

An acute eye irritation study was conducted on three albino rabbits using test substance Niccanon ZP700. The undiluted test substance (0.1 mL) was placed into the conjunctival sac of the right eye of each animal selected for testing. All treated eyes were washed with room temperature DI water for one minute immediately after recording the 24-hour observation.

The number of animals testing "positive" for each parameter (according to the Legend to Table 1) over the number of animals tested is presented below.

	Time After Treatment				
	Hours				Day
	1	24	48	72	4
Cornea					
Opacity	0/3	0/3	0/3	0/3	0/3
Iritis	0/3	0/3	0/3	0/3	0/3
Conjunctivae					
Redness	0/3	0/3	0/3	0/3	0/3
Chemosis	0/3	0/3	0/3	0/3	0/3

There were no positive effects exhibited in any eyes at 48 hours after treatment. The test substance is rated minimally irritating and assigned to Toxicity Category III.

INTRODUCTION

The objective of this study was to assess the relative level of eye irritation following a single exposure of the test substance to rabbits in accordance with US EPA OCSPP 870.2400, which is intended to meet testing requirements of FIFRA 7 USC 136, et seq, and TSCA 15 USC 2601; and OECD 405. This study was conducted for Nicca USA, Inc., according to the approved protocol and STILLMEADOW, Inc. SOPs. There were no deviations from the protocol that affected the quality or outcome of the study. All procedures in this study are in compliance with Animal Welfare Act Regulations. The protocol, raw data, this report and a sample of test substance are archived at STILLMEADOW, Inc. The study was initiated on 10 Jan 12, the pre-dose experimental portion began on 20 Feb 12, and the animals were treated with the test substance between 1309 and 1310 on 20 Feb 12. The in-life portion of the study was terminated on 24 Feb 12.